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**Abstract****Background:**

The rising financial burden of cancer on healthcare systems worldwide has led to increased demand for evidence-based research on which to base reimbursement decisions. Economic evaluations are an integral component of this necessary research. Ascertainment of reliable healthcare cost and quality of life estimates to inform such studies has historically been challenging, but recent advances in informatics in the UK provide new opportunities.

**Methods:**

The costs of hospital care for breast, colorectal and prostate cancer disease-free survivors were calculated over 15 months from initial diagnosis of cancer using routinely collected data within a UK National Health Service Hospital Trust. Costs were linked at patient level to patient-reported outcomes and registry-derived socio-demographic factors. Predictors of cost and the relationship between costs and patient-reported utility were examined.

**Results:**

The study population included 223 breast cancer patients, 145 colorectal and 104 prostate cancer patients. The 15 month cumulative healthcare costs were £12,595 (95% CI £11,517 - £13,722), £12,643 (£11,282 - £14,102) and £3,722 (£3,263 - £4,208) respectively. The majority of costs occurred within the first 6 months from diagnosis. Clinical stage was the most important predictor of costs for all cancer types. EQ-5D score was predictive of costs in colorectal cancer but not in breast or prostate cancer.

**Conclusion:**

It is now possible to evaluate healthcare cost using routine NHS datasets. Such methods can be utilised in future retrospective and prospective studies to efficiently collect economic data.

### **Key words**

Cancer, costs, resource use, health economics, quality of life, utilities, informatics.

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## Introduction

The cost of cancer is much discussed and of considerable relevance internationally given rising healthcare costs and financial constraint. The initial treatment period, rehabilitation and early follow-up after a new diagnosis of cancer incurs heavy resource demands on secondary care. Characterisation and prediction of these costs alongside other health outcomes is important for healthcare budget planning and service design aiming at improved efficiency. In particular economic evaluation is increasingly used to inform the allocation of scarce health resources, and many national reimbursement bodies (including the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK)) require the use of patient quality-adjusted life-years (QALYs) as an endpoint in economic evaluations (Drummond *et al*, 2005). Reliable analyses therefore require robust estimation of costs and patient quality-of-life (QoL). There have been several attempts to describe the cost of cancer using insurance claims, registry data or manual case-note audit (Karnon *et al*, 2007; Mariotto *et al*, 2011; Tilson *et al*, 2012; (Brown *et al*, 1999; Yabroff *et al*, 2008; Krahn *et al*, 2010; de Oliveira *et al*, 2013). Methods applied in the UK, where detailed claims databases do not exist, either fail to capture local variation and full data granularity, or require a heavy data collection burden; accurate and easily reproducible estimates of the true cost of care therefore remain elusive. In the UK the National Health Service (NHS) provides universal publically funded healthcare which operates financially through a system of commissioning for services. Payments for defined episodes of care are calculated using a national tariff. In an attempt to improve the accuracy and national standardisation of the methods used to calculate this national tariff, Patient Level Information and Costing Systems (PLICS) are being developed (Francisci *et al*, 2013). Local pilots promoting national standardisation of methods using PLICS are on-going, under guidance from the Department of Health. It is hoped that such systems, if fully implemented, will promote the ability to generate efficiency savings through improved service evaluation and planning (Blunt & Bardsley, 2012; Vogl, 2012). Patient-level costing systems provide new opportunities for the calculation of the complete hospital-based cost of care. By accurately capturing patient level variation they offer an

improvement over current methods which rely on coded Human Resource Groups (HRGs) and assigned national standard tariffs.

It is now accepted that assessments of patient quality of life should be embedded in routine care (Black, 2013). The NHS Patient Reported Outcome Measures (PROMS) initiative routinely collects quality of life data from a number of patient groups in England and is soon to be rolled out to cancer patients (Glaser *et al*, 2013). Identifying an efficient method to collect routine PROMs data linked to clinical and financial datasets is an essential prerequisite for robust future economic evaluation of cancer services. The electronic Patient-reported Outcomes from Cancer Survivors (ePOCS) project has designed and tested the technical and clinical feasibility of an electronic system for collecting patient-reported outcome data online and linking this with clinical cancer registry data (Ashley *et al*, 2011b); through data linkage mechanisms it is now possible to also connect cost data with PROMS data using this new system.

The primary aim of this paper is to describe the direct costs of hospital-based care for patients following a diagnosis of breast, colorectal or prostate cancer using routine NHS data. In particular, it aims to confirm the feasibility of data linkage between a new patient-level hospital finance system, electronic clinical records and electronically captured PROMs. The resulting composite dataset is then used to explore the extent to which clinical and socio-demographic factors predict NHS costs and quality of life over a 15 month period.

## **Patients and Methods**

The costs of hospital-based care for breast, colorectal and prostate cancer disease-free survivors were calculated over 15 months from initial diagnosis of cancer using data collected during a feasibility study of the ePOCS system. The ePOCS system is a novel electronic system for collecting patient reported outcomes online and linking them with clinical cancer registry data. The feasibility study included collection of patient clinical, socio-demographic, cost and QoL data, which were used

in this analysis to explore total 15-month cumulative costs, cost predictors, and patient utility for disease-free survivors. Comprehensive accounts of the design and development of the ePOCS system, and the protocol and results of the feasibility study have been published open-access (Ashley *et al*, 2011a, 2013). In brief, English-literate adult patients within six months of a diagnosis of early breast, colorectal or prostate cancer being treated with curative intent were recruited from Leeds Teaching Hospitals NHS Trust (LTHT) and Calderdale & Huddersfield NHS Foundation Trust (CHFT). Eligible patients were identified during routine multidisciplinary meetings and/or through consultation of medical notes by NHS research nurses and/or oncology clinicians. The recruitment period was November 2010 to September 2011. Participants were asked to complete PROMs online using the ePOCS system at three time points: T1, within 6 months of diagnosis, T2 at 9 months post-diagnosis and T3 at 15 months post-diagnosis. The PROMs data were linked with patients' clinical registry data and stored in the National Cancer Data Repository.

The cost analysis included all hospital-based costs incurred over the 15-month follow-up period in the LTHT population. Day zero was defined as the date of diagnosis, recorded from the medical notes by the research nurse at the time of patient consent to the ePOCS study. Patients were diagnosed between May 2010 and September 2011. Costs were adjusted to the common base year of 2011-12 using the Personal Social Services Research Unit (PSSRU) Hospital and community health services (HCHS) pay and prices index. Confidence intervals were calculated for all analyses using the bootstrap method. Analysis of costs was conducted using regression analysis performed on log-costs, which were approximately normally distributed and did not contain zeros, using the ordinary least squares method. The explanatory variables age, gender, oncological stage, Index of Multiple Deprivation (IMD) and baseline EQ-5D (T1) were established a priori; all of which were included in univariate and multivariate analyses. Complete case analysis was used for individual EQ-5D regressions. The complete 15 months of follow-up was available for all patients. Patients who died or suffered a cancer relapse (i.e. ceased to be disease free) during this period were identified from the clinical record and excluded on the grounds that this study reports the outcomes specific to

disease-free survivors. All analysis was carried out using the R statistical software package version 3.0.0 (R *et al*, 2009).

### ***Data capture and linkage***

The cost analysis was based on finance data from patients recruited at LTHT only, due to the fact that PLICS data was unavailable for patients recruited at CHFT. PROMs data was available from both LTHT and CHFT; the analysis of patient utility therefore utilized data from patients recruited at both LTHT and CHFT.

*1. Clinical data:* The LTHT Oncology department uses a computer-based system called Patient Pathway Manager (PPM) which links the various clinical data systems within the LTHT and maintains an electronic patient record. PPM includes information on demographics, pathology, radiology, surgery, chemotherapy and radiotherapy. The ePOCS study information was also held within PPM allowing internal linkage of ePOCS study ID, NHS number and other identifiers (Newsham *et al*, 2011).

*2. Finance data:* Patient records within LTHT from PPM were individually linked to costs held within the local pilot database of the national PLICS scheme using each patient's NHS number. This provides a cost for hospital-based accident and emergency department visits, outpatient attendances and inpatient stays. Individual care episodes are coded using the national HRG version 4 codes. HRG costing uses a mixture of (a) top down costing – where cost pools (used to collect indirect and overhead costs) are allocated to HRGs using the total cost of that cost pool weighted for each HRG based upon the best available data and, (b) bottom up costing – which builds up the costs of an HRG from known local expenditure (e.g. prosthetics in hip replacement) HRGs (Department of Health Payment by Results team, 2012). HRG codes include the average cost of intravenous and oral chemotherapies.



3. *Socioeconomic data:* A marker of socio-economic status was ascertained by calculating IMD scores and quintiles from patients' postcodes recorded in PPM; the first quintile contains patients living in the most deprived areas and the fifth quintile contains patients living in the least deprived areas (Department for Communities and Local Government, 2011).

4. *Patient Reported Outcome data:* Over the three time-points participants treated at LTHT and CHFT were asked to complete a range of PROMs, which assessed patients' psychosocial and socio-demographic status (e.g. education level, employment status etc.), quality-of-life and disease specific (breast, colorectal and prostate cancer) variables. The analysis presented here utilizes PROMs data on patient health status as measured by the EQ-5D version 2 questionnaire, collected at T1, T2 and T3. Complete case analysis was used to maximise reproducibility in future studies that build on this pilot.

The EQ-5D questionnaire measures health status across five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Respondents specify whether they have no problems, some problems or severe problems within each domain, on the day of response. Utility scores were derived from the EQ-5D responses using preferences for health states elicited from the UK general public (The EuroQol Group, 1990; Gudex *et al*, 1995). A maximum utility score of 1 represents the state of being in full health; zero represents the state of being dead. The EQ-5D has been used widely in cancer studies (Pickard *et al*, 2007b), and is regarded as the gold-standard measure of quality of life in the UK as specified by NICE for the calculation of QALYs. We compared patients' utility scores with age- and sex-matched population norms obtained from a survey of the UK population (Kind *et al*, 1998).

Ethical approval was given for the ePOCS study from the NHS Leeds (East) Research Ethics Committee (10/H1306/65). Patients provided written informed consent.

## Results

### *Patient characteristics*

In total there were 636 patients consented into the ePOCS study across LTHT and CHFT. The mean patient age was 63 (range 23-92). Full details of the patient demographics and baseline characteristics are available in the open-access ePOCS study feasibility report (Ashley *et al*, 2013). There were 297 patients with breast cancer, 192 with colorectal cancer and 147 with prostate cancer. Patients not classified as survivors within the 15 month study period were excluded; these included patients who developed new primary cancers, recurrent cancer or had died. The final study population meeting eligibility consisted of 223 patients with breast cancer, 145 with colorectal cancer and 104 with prostate cancer from LTHT, and 68 with breast cancer, 19 with colorectal cancer and 36 with prostate cancer from CHFT (see Figure 1). Baseline patient characteristics are described in Table 1. Overall, the mean age was 56 (median 55, standard deviation (sd) 10.7) for the breast patients, 63 (median 63, sd 9.1) for the colorectal patients and 65 (median 65, sd 6.6) for the prostate patients. For the cost analysis, complete data was available. For the analysis of patient utility, over 92% of EQ-5D questionnaires were returned at 6 months across all cancers, however this dropped to around 70% at 15 months for breast and colorectal cancer, and 82% for prostate cancer. Using the NHS number alone, linkage between the LTHT PLICS finance database, the electronic clinical record and the ePOCS study database was 100%.

### *Hospital costs*

Costs for breast and colorectal cancer were similar and considerably higher than those for prostate cancer. For breast cancer patients the mean cumulative hospital costs at 6, 9 and 15 months (with 95% CIs) were £9,557 (£8,893 - £10,220), £11,175 (£10,339 - £12,059) and £12,595 (£11,517 - £13,722), respectively. For colorectal cancer the corresponding figures were £10,038 (£9,015 - £11,131), £11,809 (£10,551 - £13,109) and £12,643 (£11,282 - £14,102) and for prostate cancer £2,807 (£2,398 - £3,233), £3,407 (£2,977 - £3,846) and £3,722 (£3,263 - £4,208). In each cancer at

least 75% of the total costs at month 15 were incurred by month 6. Figure 2 illustrates the decline in costs over time in all cancers with small rises around the 6 and 12 month follow-up visits.

The mean costs by subgroup suggest that the below 65 age group incurred greater costs than the 65 and over group and that costs increase with disease stage (Figure 3). Tables 2 and 3 include the univariate and multivariate analyses, respectively, predicting 15 month costs. In each case disease stage appears to be the strongest predictor of costs.

### ***Utility***

Figure 4 depicts the mean EQ-5D score at 6, 9 and 15 months for each of the three cancer types. The mean EQ-5D scores for patients with each cancer type increased over time, generally plateauing after one year from diagnosis. Breast cancer patients had the worst utility and the smallest improvements over time, which may reflect more aggressive adjuvant treatment over a longer time period compared to the two other cancer types. Older breast cancer patients also had higher utility than younger patients across the three time-points, possibly for the same reasons. There was a trend suggesting that those living in areas of higher deprivation (lower IMD groups) had lower quality of life scores compared with those living in more affluent areas. However, the multivariate regression of the EQ-5D scores (results in supplementary material) found no significant predictors of utility at any time-point for any cancer.

A full breakdown of the cumulative costs and EQ-5D score at 6, 9 and 15 months from diagnosis for each tumour type, clinical subgroups and treatment modalities is provided in the supplemental appendix. EQ-5D score at T3 demonstrated only minimal correlation with cumulative costs with a Pearson's correlation coefficient of -0.06 for breast cancer, -0.20 for colorectal cancer and -0.10 for prostate cancer. A low EQ-5D score at T1 was associated with higher 15 month cumulative costs but this only reached statistical significance in univariate and multivariate analysis for colorectal cancer (Tables 2 and 3).

Comparisons with population norms indicated that breast cancer patients had significantly lower EQ-5D score than an age- and sex-matched reference population. Conversely, prostate cancer patients were found to have significantly higher scores than the reference population. No significant difference was found for colorectal cancer patients (Table 4).

## Discussion

Traditionally cost and cost-effectiveness analyses in the UK have employed techniques such as hand searching patient records, asking patients to complete resource use questionnaires, or use of a combination of different methods from diverse sources in order to collect cost and outcomes data (Karnon *et al*, 2007). For studies with large sample sizes and longitudinal analyses these methods are particularly time consuming and have the potential for bias due to discrepancies in records both within and between facilities. More recently, use of Hospital Episode Statistics (HES) has gained popularity within cost analysis (Gaughan *et al*, 2012). HES provides electronic access to over 125 million outpatient, inpatient and accident and emergency attendances in England and is increasingly used for economic analysis negating to some extent the need to manually collect details of resource use from patient records. However, there has been debate over the completeness of HES data and constraints in the range of activity covered (Spencer & Davies, 2012). In addition, manual hand searching, patient questionnaires and HES all require unit costs to be assigned to the resource use, described as a 'top-down' costing approach. Use of PLICS data for this type of economic evaluation is based on local 'bottom-up' costing techniques, where the costs of specific procedures or care episodes reflect the real local expenditure required to provide them. Analysis using a PLICS database is less onerous, time-consuming and costly than hand searching patient records and is unlikely to suffer potential difficulties associated with recall bias. Local unit costs are included in each PLICS database and the granularity and range of the data is likely to have fewer constraints than HES data.

In the UK, the patient level information and costing system (PLICS) initiative led to coordinated local piloting in 2009 with the primary objective of providing NHS organizations a better understanding of their drivers of costs (Department of Health, 2011). The intention of this system is to provide an electronic means by which to measure the resources consumed by individual patients. Such data may then be used to understand variations in services. When linked with clinical care and outcomes data, improved clinical ownership of resource decisions and evidence-based analysis also becomes

possible (Francisci *et al*, 2013). PLICS is not compulsory across the NHS, and by 2010 few Trusts had implemented the system. Early indications suggest it is a useful tool to provide accurate data on spending against income (Blunt & Bardsley, 2012). This is the first study to assign costs to the clinical cancer care pathway using linkage between PLICS and clinical datasets. It also has the added advantage of linked quality-of-life data, providing proof of concept for a comprehensive routine electronic dataset for technology evaluation.

This study adds substantially to the current limited literature on the costs of hospital-based cancer care using robust, efficient and reproducible methods. To our knowledge this is the first UK study to report costs in this manner for the initial year after diagnosis and certainly the largest study of its kind to date. Two previous studies have looked at the costs of recurrent breast cancer with estimates between £12,000 and £25,000 for the first year after diagnosis of a recurrence in patients with a previously treated breast cancer (Karnon *et al*, 2007; Thomas *et al*, 2009). Both studies use a top-down HRG based costing method. This compares with our study's headline 15 month cost for new breast cancer patients of £12,595.

The cost analysis was based on data from one of the biggest NHS trusts in the country, which offers a range of both general and specialist hospital services. The results are therefore likely to be broadly generalizable across the UK population to similar sized populations. Care should be taken when attempting to apply these cost results in a non-UK context, as the specific configuration of individual national health care service provision- which has a major impact on how and where costs are likely to be incurred- can vary significantly from country to country. An advantage of this study is that it enables adjustment of both costs and EQ-5D scores based on clinical and demographic factors, allowing greater representations of local populations with well-defined characteristics.

Overall this analysis found that baseline staging and related clinical characteristics were the strongest predictors of hospital costs. Within breast cancer significant predictors were lymph node status, grade and molecular markers (HER2 and hormone status); for colorectal cancer, Dukes

classification and for prostate cancer the Gleason score. Socio-demographic variables were of less importance as predictors of cost. There was no clear association between treatment costs and Index of Multiple Deprivation (IMD). This is surprising given that health inequalities have previously been seen to be associated with poorer health and health outcomes and higher treatment costs (Marmot *et al*, 2010). It may, however, be explained by a limitation of the study, whereby all people involved in ePOCS had to be able to access the internet. Inevitably this meant that the trend common in routine clinical trials, whereby fewer older people living in areas of greater deprivation enroll in studies, was exacerbated in this study (Sateren, 2002; Murthy *et al*, 2004). There was a significant difference in IMD quintile between those who consented and refused study participation ( $P < .001$ ) and IMD quintile was the only significant predictor of retention in a regression analyses. In addition, our analysis showed no correlation between IMD and staging in contrast to evidence to suggest IMD predicts clinical outcome (Downing *et al*, 2007).

Our univariate analyses showed significant differences in costs by age, but these differences were no longer significant (at the 99% level) in the multivariate analyses. Despite the lack of statistical significance a clear trend exists suggesting that older patients (65 and over) are associated with lower costs than younger patients. In the case of breast cancer this may be explained by younger patients presenting with higher disease stage, as well as more aggressive treatment of younger patients. In colorectal and prostate cancer it is unclear why this might be and whether this is related to demand-side (patients actively consuming more health care resources – e.g. contacting the doctor more frequently) or supply-side factors (healthcare professionals providing more health care resources – e.g. conducting more tests or suggesting more frequent visits). The absence of information about co-morbidity is a clear limitation of this study as it is likely that co-morbidity contributes to differences in costs between age groups.

The multivariate regression of the EQ-5D scores found no significant predictors of quality of life at any time-point for the three cancer types. The lack of significance may be a function of the relatively

limited sample size, particularly for the EQ-5D analysis due to the limitation of missing data. The descriptive analysis on the EQ-5D by subgroup did provide some interesting results. In line with expectations, the quality of life for patients with the three cancer types increased over time from diagnosis and radical treatment. Breast cancer patients appear to have the worst quality of life and the smallest improvements in quality of life over time. This may be related to the continuing psychological impact of mastectomy, especially in a sample that is young relative to the other cancer-type patients. There was the interesting finding that younger women with breast cancer have worse quality of life than older women. This confirms the findings in this regard of a number of other studies (Calman, 1984; Hopwood *et al*, 2007). In contrast, conventional wisdom in non-breast cancer patients based on many analyses of EQ-5D data including population norms and Health Survey for England data has concluded that quality of life declines with age (Maheswaran *et al*, 2013). Indeed we see in the prostate and colorectal cancer groups that older patients have lower EQ-5D scores, even when stratified by gender. It is not clear why this quality of life reversal by age group exists in breast cancer. It is possible that the impact of cancer is greater in younger patients due to greater psychological distress, or appears greater due to questionnaire responses being reference based (to the health of similarly aged-peers) or expectation-based. A number of mean between-group differences in quality of life appeared non-trivial and in the order of magnitude of a difference that could be considered important (between 0.06-0.12) (Pickard *et al*, 2007a). These include the differences between breast and prostate cancer patients, differences between age groups in breast cancer and between the highest and lowest IMD groups. The quality of life of the three sets of cancer patients appears roughly in line with population norms with the exception that younger breast cancer patients experience a decrement and the patients with prostate cancer have consistently higher scores. The colorectal cancer patients are almost the same as the population norms. The recruitment and retention within the ePOCS study is biased due to both deprivation and age, in common in many trials and exaggerated in ePOCS due to the reliance on information technology. This may explain higher than expected quality of life. The association seen between T1



EQ-5D scores and cumulative costs is intuitive given that more intensive treatments such as chemotherapy and radiotherapy may cost more and increase morbidity.

LTHT's PLICS system is constructed using nationally recognised costing principles and methods, supplemented where appropriate by locally determined rules and arrangements relevant and appropriate to PLICS, and having been determined in consultation with divisional clinical, operational and finance representatives initially and since by regular review. Effort to date has predominantly been focussed on refining the inputs to the system and, at the time of writing, there has been no systematic, widespread review of PLICS outputs across LTHT amongst operational and clinical staff. This is something which, following a recent Trust restructuring and the creation of Clinical Service Units, the Trust is now embarking upon using 2012-13 PLICS data. Until this systematic validation takes place LTHT PLICS data must be treated with caution. Additionally the Trust is conscious of a number of areas of NHS service provision in which the linking of costs to patients is still not possible, such as catering services and housekeeping; this may impact differentially on services evaluated.

This analysis considered hospital post-diagnosis costs over a 15-month follow-up period. A full analysis of costs requires additional consideration of both primary and community care costs, as well as costs incurred pre-diagnosis and in the longer term. We will be attempting to quantify these additional costs in future planned analyses.

This paper has described an analysis based on data generated by employing a novel method of capturing patient-reported outcome data and linking that with clinical and cost data from hospitals. The feasibility and utility of such data linkage now being evident, further efforts to routinely collect and link such data is encouraged. The results described here will be of use to health economic modellers requiring cost and utility estimates to populate decision-analytical models. The results have implications for health economic analysis and modelling in cancer. Firstly, costs decline rapidly after the initial treatment phase but have small peaks around the routine visit time-points; thus analysts should have differential cost estimates in year 1 versus subsequent years. Unsurprisingly,

costs differ by disease stage but also more unexpectedly by age with younger patients being associated with greater costs. The latter point is worthy of further investigation. The quality of life of patients recovering from cancer does not appear substantively different from age-specific population norms with the exception of younger women with breast cancer, although this finding may be a result of potential patient selection bias as previously discussed. Future economic analyses of breast cancer interventions should bear in mind the quality of life decrement that accompanies breast cancer in younger groups in addition to the time-varying and subgroup-varying nature of secondary healthcare costs.

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